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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,524	05/10/2001	Su-Chen Chang	205032000420	6780

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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,524	CHANG ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003 and 05 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-23,26-28,34 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23,26-28,34 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/5/04 has been entered.

Amendment Entry

2. Applicant's amendment and response filed 12/15/03 is acknowledged and has been entered. Claims 24, 25, and 29-33 have been cancelled. Claims 21, 23, 26, and 28 have been amended. Claims 34 and 35 have been added. Accordingly, claims 21-23, 26-28, 34, and 35 are pending and are under examination.

Rejections Moot

3. The rejections of claims 24, 25, and 29-33 are now moot in light of Applicant's cancellation of the claims.

4. In light of Applicant's amendment, the rejection of claims 21-33 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.

5. In light of Applicant's amendment, the rejection of claims 21-33 under 35 U.S.C. 112, first paragraph, is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 26-28 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite in being redundant in reciting, "inhibiting the activation of ... gpIIb/IIIa activation."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 21-23, 26-28, 34, and 35 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by Sollevi (US Patent 5,731,296).

Sollevi discloses administering to human beings an effective amount of adenosine by continuous infusion for use in treating various disease conditions (see Abstract). Sollevi specifically reports that adenosine has a variety of biological effects

whether it is endogenously or exogenously administered, including inhibition of platelet aggregation (anti-aggregatory effect), antithrombotic effect (inhibit clot formation), vasodilation, peripheral and cardiovascular effects, and hypotensive activity. Accordingly, adenosine is administered for use in treating thromboembolic disorders such as hypertension, arterial thrombosis, ischemia, and peripheral vascular diseases (see column 1, lines 23-36, column 2, lines 39-64, column 3, lines 11-15, and column 20, lines 12-28). Adenosine is administered to a patient as a composition in any pharmaceutically acceptable carrier, i.e. diluent such as isotonic saline, or form (see column 3, lines 27-61). Sollevi also discloses administering adenosine in combination with another antithrombic such as heparin for the purpose of platelet protection during cardiopulmonary bypass (see Example VI).

While Sollevi is silent in teaching that adenosine effectively inhibits activation of platelet membrane receptor protein gpIIbIIIa, the instant claims merely recite a newly discovered mechanism of adenosine, i.e. inhibition of gpIIbIIIa activation in order to inhibit platelet aggregation and thrombosis as in the (known) method taught by Sollevi. Sollevi administers the adenosine into mammals, including humans, to achieve the same or nearly the same end result; that is, to induce platelet aggregation or thrombosis, albeit by the mechanism of vasoconstriction. Additionally, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). Newly discovered property and result of known processes and compositions directed to the

same purpose are not patentable because such results are inherent.

8. Claims 21-23 and 34 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by Wang et al. (FASEB Journal 9 (3) : page A322 (1995)).

Wang et al. teach that administration of adenosine has an antithrombotic effect in dogs as in vivo models of arterial thrombosis. Wang et al. further administer adenosine in combination with aspirin as antithrombotic.

Wang et al. is silent in teaching that adenosine is effective in inhibiting the activation of platelet membrane receptor protein gpIIbIIIa.

While Wang is silent in teaching that adenosine effectively inhibits activation of platelet gpIIbIIIa, the instant claims merely recite a newly discovered mechanism of adenosine, i.e. inhibition of gpIIbIIIa activation in order to inhibit platelet aggregation and thrombosis as in the (known) method taught by Wang. Wang administers the adenosine into mammals, including humans, to achieve the same or nearly the same end result; that is, to induce platelet aggregation or thrombosis, albeit by the mechanism of vasoconstriction. Additionally, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). Newly discovered property and result of known processes and compositions directed to the same purpose are not patentable because such results are inherent.

Response to Arguments

8. Applicant's arguments filed 12/15/03 have been fully considered but they are not persuasive.

A) Applicant argues that Sollevi or Wang fails to teach or suggest each and every element of the claimed invention. Applicant specifically argues that Sollevi or Wang fails to teach or suggest the use of adenosine to inhibit the activation of gpIIbIIIa and that Sollevi or Wang instead uses adenosine as a potent vasodilatory agent. While Applicant concedes that Sollevi suggests that adenosine has an inhibiting effect on platelet aggregation, Applicant contends that there is no indication that this is a separate function from its vasodilatory effect; thus concludes that adenosine as taught by Sollevi or Wang acts to inhibit platelet aggregation by none other than vasoconstriction. According to Applicant, since Sollevi does not teach or suggest non-vasocontriction mediated conditions that trigger thromboembolic events, Sollevi or Wang neither anticipate nor render obvious the claimed invention.

In response, Sollevi at column 3, lines 12-15 teaches that adenosine **is** useful in inhibiting clot formations, and at column 20, lines 20-23 that adenosine **has** an inhibiting effect on platelet aggregation. Wang also teaches that adenosine has an antithrombotic effect. Thus, responsive to Applicant's argument that Sollevi or Wang fails to teach that the inhibition is due to the effect of adenosine on gpIIbIIIa activation, Applicant fails to provide that the adenosine composition in the methods of both of Sollevi or Wang did not function to inhibit platelet aggregation or thrombosis by way of inhibiting the

activation of gpIIbIIIa, in addition to its vasoconstrictive effect. Absent evidence to the contrary, the adenosine administered to mammals, including humans in the method of Sollevi or Wang, effectively functioned to inhibit the activation of gpIIbIIIa in addition to its vasoconstricting effects, in order to inhibit platelet aggregation or thrombosis, as recited in the claimed invention.

Additionally, although Sollevi or Wang is silent about the property of adenosine that inhibits platelet gpIIbIIIa activation which induces platelet aggregation and thrombosis, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). [I]t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990) [T]he mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. Bristol-Myers Squibb Company v. Ben Venue Laboratories 00-1304 (CAFC 4/20/01). Preamble language in claims of patents directed to administration of compositions are expressions of purposes and intended results, and

as such are non-limiting, since language does not result in manipulative difference in steps of claims; case does not present situation in which new use of process should be considered limiting because it distinguishes process over prior art. In re Hirao 190 USPQ 15, 16-17, (CCPA 1976) held that the preamble was non-limiting because it merely recited the purpose of the process, which was fully set forth in the body of the claim.

On this record, it is reasonable to conclude that the same mammal or human is being administered the same adenosine, by the same mode of administration, in the same effective amount, in both the instant claims and the prior art reference. The fact that Applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Applicant is reminded that no more of the reference is required than that it sets forth the composition and effect of the invention. The claimed functional limitations would be inherent properties of the referenced composition and method to administer adenosine for inhibiting platelet gpIIbIIIa activation to thus, induce platelet aggregation and thrombosis.

9. For reasons aforementioned, no claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703)

305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
May 13, 2004 GG

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641